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TECH CENTER 1600/2900IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dean L. Engelhardt et al.

Serial No. 08/486,069

Group Art Unit: 1631

Filed: June 7, 1995

Examiner: Ardin Marschel,  
Ph.D.

Title: NUCLEIC ACID SEQUENCING PROCESSES  
USING MODIFIED NUCLEOTIDES OR  
NUCLEOTIDE ANALOGS, AND OTHER  
PROCESSES FOR NUCLEIC ACID DETECTION  
AND CHROMOSOMAL CHARACTERIZATION  
USING SUCH MODIFIED NUCLEOTIDES OR  
NUCLEOTIDE ANALOGS (As Amended)

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TRANSMITTAL  
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

FILED VIA EXPRESS MAIL

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Sir:

Transmitted herewith is a Supplemental Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

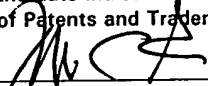
Dean L. Engelhardt et al.

Serial No.: 08/486,069

Filed: June 7, 1995

Page 2 [Transmittal for 4th Supplemental Information Disclosure Statement  
-- September 19, 2001]



EXPRESS MAIL CERTIFICATE	
"Express Mail" Label No.:	<u>EL492433496US</u>
Deposit Date:	<u>September 19, 2001</u>
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231	
 Ronald C. Fedus Reg. Exhibit 32,567	<u>SEPT 19 2001</u> Date

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Page 3 [Transmittal for 4th Supplemental Information Disclosure Statement  
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1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:

2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.

3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_.

4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:

☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.

☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.

☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.

5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.

6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):

☐ A check in the amount of \$240.00 is enclosed in payment of the fee.

Dean L. Engelhardt et al.

Serial No.: 08/486,069

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Page 4 [Transmittal for 4th Supplemental Information Disclosure Statement  
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☒ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-5(D8)(C2). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:

a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and

b. the attached petition requesting consideration of this Information Disclosure Statement; and

c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.

8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:

a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;

b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.

c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

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Page 5 [Transmittal for 4th Supplemental Information Disclosure Statement  
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I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

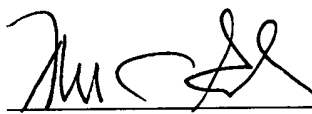
10. ☐ A check in the amount of \$130.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

☐ Charge the fee under 37 C.F.R. 1.17(i)(1) to Deposit Account No. 05-1135. Order No. \_\_\_\_\_. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: September 19, 2001

By:   
\_\_\_\_\_  
Ronald C. Fedus  
Attorney for Applicants  
Registration No. 32,567

Mailing Address:  
ENZO DIAGNOSTICS, INC.  
c/o Enzo Biochem, Inc.  
292 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
Telephone: (212) 583-0100  
Telefax: (212) 583-0150



THE UNITED STATES PATENT AND TRADEMARK OFFICE

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FOR NUCLEIC ACID DETECTION AND )  
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NUCLEOTIDES OR NUCLEOTIDE )  
ANALOGS (As Previously Amended) )

Group Art Unit: 1631

Examiner: Ardin H. Marschel,  
Ph.D.

527 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
September 19, 2001

**FILED VIA EXPRESS MAIL**

Honorable Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following seventy-three (73) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

Enz-5(D8)(C2)

Dean L. Engelhardt et al.

Serial No.: 08/486,069

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Page 2 [Transmittal for 4th Information Disclosure Statement  
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**EXPRESS MAIL CERTIFICATE**

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Ronald C. Fedus

SEPT 19 2001  
Date

Reg. Exhibit 32,567

Dean L. Engelhardt et al.

Serial No.: 08/486,069

Filed: June 7, 1995

Page 3 [Transmittal for 4th Information Disclosure Statement  
-- September 19, 2001]

1. Carpino, et al., U.S. Patent No. 3,906,031 [Exhibit 1];
2. Chirikjian, U.S. Patent No. 4,119,521 [Exhibit 2];
3. Kaplan et al., U.S. Patent No. 4,151,065 [Exhibit 3];
4. Khanna et al., U.S. Patent No. 4,318,846 [Exhibit 4];
5. Itakura, U.S. Patent No. 4,373,071 [Exhibit 5];
6. Catsimpoolas, U.S. Patent No. 4,375,401 [Exhibit 6];
7. Itakura, U.S. Patent No. 4,401,796 [Exhibit 7];
8. Caruthers et al., U.S. Patent No. 4,415,732 [Exhibit 8];
9. Hudson et al., U.S. Patent No. 4,474,948 [Exhibit 9];
10. Urdea et al., U.S. Patent No. 4,483,964 [Exhibit 10];
11. Caruthers et al., U.S. Patent No. 4,500,707 [Exhibit 11];
12. Urdea et al., U.S. Patent No. 4,517,338 [Exhibit 12];
13. Gross et al., U.S. Patent No. 4,534,647 [Exhibit 13];
14. Zelinka et al., U.S. Patent No. 4,598,049 [Exhibit 14];
15. Miyoshi et al., U.S. Patent No. 4,667,025 [Exhibit 15];
16. Caruthers et al., U.S. Patent No. 4,668,777 [Exhibit 16];
17. Fung et al., U.S. Patent No. 4,757,141 [Exhibit 17];
18. Smith et al., U.S. Patent No. 4,849,513 [Exhibit 18];
19. Fung et al., U.S. Patent No. 4,855,225 [Exhibit 19];
20. Ruth, U.S. Patent No. 4,948,882 [Exhibit 20];
21. Smith et al., U.S. Patent No. 5,015,733 [Exhibit 21];



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Page 4 [Transmittal for 4th Information Disclosure Statement  
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22. Smith et al., U.S. Patent No. 5,118,800 [Exhibit 22];
23. Smith et al, U.S. Patent No. 5,118,802 [Exhibit 23];
24. Kostichka et al, U.S. Patent No. 5,162,654 [Exhibit 24];
25. Smith et al, U.S. Patent No. 5,171,534 [Exhibit 25];
26. Fung et al., U.S. Patent No. 5,212,304 [Exhibit 26];
27. Fung et al, U.S. Patent No. 5,258,538 [Exhibit 27];
28. Bergot et al., U.S. Patent No. 5,366,860 [Exhibit 28];
29. Ruth et al, U.S. Patent No. 5,541,313 [Exhibit 29];
30. Japanese Patent No. 59-44648, Assigned to Sanso Seisakusho KK [Exhibit 30] [Note: No English language translation or English language equivalent is available or has been provided];
31. Japanese Patent No. 59-93100 [Exhibit 31] [Note: No English language translation or English language equivalent is available or has been provided];
- 31A. Miyoshi, et al., U.S. Patent No. 4,667,025 [Exhibit 31A] [Note: This is a member of the family of patents related to Exhibit 31];
- 31B. Miyoshi, et al., U.S. Patent No. 4,820,812 [Exhibit 31B] [Note: This is member of the family of patents related to Exhibit 31];
- 31C. Miyoshi, et al., U.S. Patent No. 4,789,737 [Exhibit 31C] [Note: This is a member of the family of patents related to Exhibit 31];
32. Japanese Patent No. 59-126252 [Exhibit 32];
- 32A. Shiraishi H., European Patent No. EP 0 115 777 B1 [Exhibit 32A] [Note: This is a member of the family of patents related to Exhibit 32 above; no English language translation is available];

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33. Japanese Patent No. 60-161559, Assigned to Hitachi Ltd. and Mitsubishi Chem. Ind. Ltd. [Exhibit 33] [Note: No English language translation or English language equivalent is available or has been provided];

34. Japanese Patent No. 60-242368, Assigned to Hitachi Ltd. [Exhibit 34] [Note: No English language translation or English language equivalent is available or has been provided];

35. UK Patent No. GB 2153356 [Exhibit 35];

36. WIPO Patent No. WO 83/03260 [Exhibit 36];

37. WIPO Patent No. WO 86/06726 [Exhibit 37];

38. WIPO Patent No. 86/07361 [Exhibit 38];

39. European Patent No. EP 0 068 875 [Exhibit 39];

40. European Patent No. Ep 0 070 687 [Exhibit 40];

41. European Patent No. EP 0 090 789 [Exhibit 41];

42. European Patent No. EP 0 097 341 [Exhibit 42];

43. European Patent No. EP 0 261 283 [Exhibit 43];

44. Japanese Patent No. 49-126395 [Exhibit 44] [Note: No English translation or English language equivalent is available or has been provided];

45. Japanese Patent No. 57-209297 [Exhibit 45];

45A. Ward et al., U.S. Patent No. 5,328,824 [Exhibit 45A] [Note: This is a member of the family of patents related to Exhibit 45 above];

45B. Ward et al., U.S. Patent No. 5,449,767 [Exhibit 45B] [Note: This is a member of the family of patents related to Exhibit 45 above];

45C. Ward et al., U.S. Patent No. 5,476,928 [Exhibit 45C] [Note: This is a member of the family of patents related to Exhibit 45 above];

46. Japanese Patent No. 58-502205, Assigned to Cent. Nat. Rech. Sci.; Institut Pasteur; Kourilsky et al. [Exhibit 46] [Note: No English translation or English language equivalent is available or has been provided];

47. Maxam, A.M. and Gilbert, W., "Sequencing End-Labeled DNA with Base-Specific Chemical Cleavages," Methods in Enzymology 65:499-595 (1980) [Exhibit 47];

48. Sanger, F. et al., "DNA sequencing with chain-terminating inhibitors," Proc. Natl. Acad. Sci. (USA) 74(12):5463-5467 (1977) [Exhibit 48];

49. Akusjarvi G., and Pettersson, U., "Nucleotide sequence at the junction between the coding region fo the adenovirus 2 hexon messenger RNA and its leader sequence," Proc. Natl. Acad. Sci. (USA) 75(12):5822-5826 (1978) [Exhibit 49];

50. Kitamura N. and Wimmer E., "Sequence of 1060 3'-terminal nucleotides of poliovirus RNA as determined by a modification of the dideoxynucleotide method," Proc. Natl. Acad. Sci. (USA) 77(6):3196-3200 (1980) [Exhibit 50];

51. Bouloy M. et al., "Cap and Internal Nucleotides of Reovirus mRNA Primers Are Incorporated into Influenza Viral Complementary RNA During Transcription In Vitro," Journal of Virology 32(3):895-904 (1979) [Exhibit 51];

52. Plotch S.J. et al., "Transfer of 5'-terminal cap of globin mRNA to influenza viral complementary RNA during transcription *in vitro*," Proc. Natl. Acad. Sci. (USA) 76(4):1618-1632 (1979) [Exhibit 52];

53. Kagakukai ed., "Fluorescence tagging" Biochemistry Experiments Course 2, Nucleic Acid Chemistry III, pages 299-317 (1977) [Exhibit 53] [Note: This document is not yet available and has not been provided];

54. Yang, C-H., and Soll, D., "Studies of Transfer RNA Tertiary Structure by Singlet-Singlet Energy Transfer," Proc. Natl. Acad. Sci. (USA) 71(7):2838-2842 (1974) [Exhibit 54];

55. Yoshioka et al., "Method for determining a DNA nucleotide sequence I," Cell Engineering 1(1):93-101 (1982) [Exhibit 55] [Note: This document is not yet available and has not been provided];

56. Lee, D.C. and Roeder, R.G., "Transcription of Adenovirus Type 2 Genes in a Cell-Free System: Apparent Heterogeneity of Initiation at Some Promoters," Molecular and Cellular Biology 1(7):635-651 (1981) [Exhibit 56];
57. Nomiya et al., "Method for determining a DNA nucleotide sequence II," Cell Engineering 1(2):105-115 (1982) [Exhibit 57] [Note: This document is not yet available and has not been provided];
58. Draper, D.E. and Gold, L., "A Method for Linking Fluorescent Labels to Polynucleotides: Application to Studies of Ribosome-Ribonucleic Acid Interactions," Biochemistry 19(9):1774-1781 (1980) [Exhibit 58];
59. Douglass et al., "Methods and instrumentation for fluorescence quantitation of proteins and DNA's in electrophoresis gels at the 1 ng level," Electrophoresis '78 N. Catsimopoulos, ed., pages 155-165 (1978) [Exhibit 59] [Note: This document is not yet available and is not provided];
60. Gilbert W., "DNA-sequenzierung und gon-struktur (Nobel-Vortrag)" Angewandte Chemie 93:1037-1046 (1981) [Exhibit 60] [Note: This document is not yet available and is not being provided; however, an English language translation is provided as Exhibit 66A below];
- 60A. Gilbert W., "DNA Sequencing and Gene Structure," Science 214(18):1305-1312 (1981) [Exhibit 60A] [Note: This document is an English language equivalent of the above-noted document 66];
61. Maxam, A.M. and Gilbert, W., "Sequencing End-Labeled DNA with Base-Specific Chemical Cleavages," Methods in Enzymology 65:499-504 (1980) [Exhibit 61];
62. Sanger et al., "DNA Sequencing With Chain Terminating Inhibitors," Proc. Natl. Acad. Sci. (USA) 74:5463-5467 (1977) [Exhibit 62];
63. Smith A.J.H., "DNA Sequence Analysis by Primed Synthesis," Methods in Enzymology 65:560-580 (1980) [Exhibit 63];
64. Barrio J.R. et al., "Fluorescent Adenosine And Cytidine Derivatives," Biochemical and Biophysical Research Communications 46(2):597-604 (1972) [Exhibit 64];

65. Eshaghpour, H. et al., "Specific chemical labeling of DNA fragments," Nucl. Acids Res. 7(6):1485-1495 (1979) [Exhibit 65];

66. Fiddes, J.C., "Isolation, cloning and sequence analysis of the cDNA for the  $\alpha$ -subunit of human chorionic gonadotropin," Nature 281(4):351-356 (1979) [Exhibit 66];

67. Guo et al., "New rapid methods for DNA sequencing based on exonuclease III digestion followed by repair synthesis," Chem. Abst. 97:162 (abstract no. 1521k) (1982) [Exhibit 67];

68. Husimi, Y. "DNA Sequences," Oyo Buturi 51(12):1400 (1982) [Exhibit 68] [Note: This document is not yet available and has not been provided];

69. Secrist, J.A. et al., "Fluorescent modification of cyclic amp spectroscopic properties and activity in enzyme systems," Science 177:279-280 (1972) [Exhibit 69];

70. Stanley et al., "A difference approach to RNA sequencing," Nature 274:87-89 (1978) [Exhibit 70] [Note: This document is not yet available and has not been provided];

71. Tsuchiya M. et al., "Developments of DNA fluorescent labeling and real-time fluorescent detection gel electrophoresis methods," Biophysics 22: 20-E-19 (1982) [Exhibit 71] [Note: This document is not yet available and has not been provided];

72. Ulanov et al., "Electron microscopic determination of guanosine localization in DNA," Chem. Abst. 67:1692 (1967) (abstract no. 17910c) [Exhibit 72] [Note: This document is not yet available and has not been provided]; and

73. Titus, J.A. et al., "Texas Red, a hydrophilic red-emitting fluorophore for use with fluorescein in dual parameter flow microfluorometric and fluorescence microscopic studies," Journal of Immunological Methods 50:193-204 (1982) [Exhibit 73];

The above documents [Exhibits 1-73] came to attention of Applicants attorney in a review of Smith et al., U.S. Patent No. 5,821,058, issued on October 13, 1998. The above documents were listed as "References Cited" in U.S. Patent No. 5,821,058.

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Page 9 [Transmittal for 4th Information Disclosure Statement  
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A completed Form PTO-1449 listing the 73 above-submitted documents is also attached hereto as Exhibit 74.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither suggested nor disclosed by the documents referred to above and is thus patentably distinct thereover.

Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

Dean L. Engelhardt et al.

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Respectfully submitted,

Ronald C. Fedus  
Registration No. 32,567  
Attorney for Applicants

ENZO DIAGNOSTICS, INC.  
c/o Enzo Biochem, Inc.  
527 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
Tel. (212) 583-010

\* \* \* \* \*

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Respectfully submitted,

Ronald C. Fedus  
Registration No. 32,567  
Attorney for Applicants

ENZO DIAGNOSTICS, INC.  
c/o Enzo Biochem, Inc.  
527 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
Tel. (212) 583-010

\* \* \* \* \*